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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Patrick J. Sweeney

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FOLEY & LARDNER LLP
777 EAST WISCONSIN AVENUE
MILWAUKEE, WI 53202-5306

EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/686,998	Applicant(s) SWEENEY, PATRICK J.	
	Examiner CHERYL MILLER	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 10,12,18,22,28,37,43,66 and 70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,7,9,11,13,21,23,25,27,30,32,34,38,39,41,61,63,68,69 is/are rejected.
- 7) ☒ Claim(s) 6,15 and 65 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,3,5-7,9-13,15,18,21-23,25,27,28,30,32,34,37-39,41,43,61,63,65 and 68-70.

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DETAILED ACTION

Response to Arguments

The previously indicated allowable subject matter is newly rejected herein due to the finding of additional prior art. This action is NON-FINAL.

It is noted that the Buttermann (US 2005/0113924 A1) and Malek (US 2005/0071007 A1) rejections have been maintained for some claims as the previously filed declaration did not antedate the rejected claims. The evidence submitted was insufficient to establish a conception of the invention prior to the effective date of the Buttermann reference and Malek reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). The drawings submitted did not evidence the claimed subject matter of claims 32, 34, 36, 38, 39, and 41, particularly the interchangeability of different shaped disc prostheses and having different disc prostheses of different shapes.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 21, 23, 25, 27, and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 3 and 21 require a structure that prevents rotation of the disc core relative the prosthesis endplate. This is seen to be non-enabling. This limitation was present in the original claims, thus is not new matter, however it is unclear how such a spinal system could function. Figure 1 shows the prosthesis endplate (12) to have a recess in its top surface. Figures 8-10 show an articulating disc prosthesis (40). Although it is clear that the bottom of disc prosthesis lock into prosthesis endplate, it is not clear how rotation will be prevented of the entire disc core (46). Because disc core (46) articulates through a range of motion, it would seem that only a bottom portion of the core be prevented from rotation relative the prosthetic endplate, not the top portion of the core. For the core (46) as a whole to function as a motion device, it may not (in its entirety anyway) be prevented from rotation relative the prosthesis endplate. Claims 23, 25, 27, and 30 depend upon claim 21 and inherit all problems associated with the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32, 38, and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Buttermann (US 2005/0113924 A1, cited previously). Buttermann discloses a spinal implant system (figs.15, 17, 21, 24) comprising a vertebral prosthesis (fixation member; 214 for

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example) comprising a support (224) with a first portion slidably received in a second portion (see figs) and prosthesis endplate (252), an artificial disc comprising a disc endplate (244) and disc core (242+240), the artificial disc interlocked with the prosthesis endplate (by recess and flange, morse taper connection), an a pedicle screw retainer (holes in fixation member; P0095; P0106) having top, bottom and aperture (246, 510) for a screw (310) capable of penetrating a pedicle. Buttermann discloses different disc prosthesis by having different amounts of spring and spring constants (P0025, P0139). Buttermann discloses a locking ring for securing the first portion relative the second portion of the support (c-clamps, P0117, P0125).

Claims 32, 34, 38, 39, and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Malek (US 2005/0071007 A1, cited previously). See figures 25-28. Malek discloses a support shaft (240+232) having a first portion (232) slidably received (alternate to threaded connection is disclosed a saw tooth connection thus slidable, P0049, P0071; also in the threaded connection shown, the two cylinders slide helically with respect to one another), in a second portion (240), a locking ring (237) adapted to secure the first portion to the second portion (because lock ring has notches which correspond to other notches and tabs, the notch of lock ring 237 contributes to locking the portions relative one another; see fig.28), first prosthesis endplates (286 OR 242), an artificial disc having a core (302 or 304) and disc endplate (270 or 272), the disc (270+302) coupled to the prosthesis endplate (286 or 242) by an interlocking structure (complimentary surfaces, concave/convex). Malek discloses a pedicle screw retainer (tab 268 or portion of baseplates, see P0054) for receiving a screw (270; fig.28) *capable* of extending through a pedicle. Malek discloses the endplate tray (when considered 242) screwed to the shaft

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(240+232). Malek discloses use with different disc prostheses (P0007, P0008). It is noted that the disc prostheses of claim 32 are not positively claimed, they are recited only as intended use (when implanted, method step) thus not required by the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buttermann (US 2005/0113924 A1, cited previously). Buttermann discloses the spinal prosthesis substantially as claimed (see above). Buttermann discloses the prosthesis endplate and support to be attached, however is silent to mention how they are connected. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have one of the claimed connections (threaded, snapped, or twisted), since such are common attachment means. It would be common sense to use any form of attachment, as Buttermann is silent to a specific attachment method.

Claims 1, 5, 7, 9, 11, 13, 32, 38, 61, 63, 68, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischmann et al. (US 6,375,682 B1) in view of Hedman (US 4,759,769, cited previously). Fleischmann discloses a spinal implant system (figs.2b, 3, 4b) comprising a vertebral prosthesis comprising a support (bellows 26+fluid) with a first portion

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(fluid; col.5, lines 59-64) slidably received in a second portion (26), locking ring (32) securing first portion relative second portion (lock ring allow fluid in or out, thus control relative adjustment), and prosthesis endplate (28), an artificial disc comprising a disc endplate (12) and disc core (22), the artificial disc interlocked with the prosthesis endplate (28). Fleischmann discloses the implant system substantially as claimed. Fleischmann discloses screws for attaching the device to the adjacent vertebrae (see 74, 76, fig.4a, 4b) however does not disclose specific locations of screw retainer (on the support or endplate with the hole in the perpendicular direction). Hedman teaches in the same field of spinal implant systems, the use of a tab (46) with perpendicular aperture on an endplate for attachment of a screw for better securement (col.3, lines 50-69). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Fleischmann's vertebral prosthesis with disclosure of possible anchoring means with Hedman's alternative anchoring means (tabs with perpendicular apertures considered pedicle screw retainers with top, bottom and aperture) in order to provide a prosthesis with increased anchoring capabilities.

Referring to dependent claims, Fleischmann discloses the prosthesis endplate (28) having a recess (30) adapted to interlock with the artificial disc (portion 40 of disc core). Core 22 has ball bearing which also rotation relative prosthetic endplate (28) within groove (42). Fleischmann discloses a second prosthesis endplate (lower 28, not shown in fig.1c) coupled to a second disc (lower 22+12).

It is noted that in claim 32, the prosthetic discs are not positively claimed, thus not required by Fleischmann. They are recited only as intended use (*implanted adjacent*).

Allowable Subject Matter

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Claims 6, 15, and 65 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738

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